20. (Added) The substantially purified nucleic acid molecule according to claim 16, wherein said nucleic acid molecule consists of a nucleic acid sequence of SEQ ID NO: 1 or a complement thereof.

Remarks

Non-elected claims 4, 8 and 11 have been canceled without prejudice to or disclaimer of the underlying subject matter. Claims 3 and 7 have been amended to reflect the elected SEQ ID NO: 1. Claims 12 through 20 have been added. Support for the foregoing claim amendments and new claims may be found throughout the specification, for example at page 9, lines 12-14, at page 16, line 12 through page 17, line 10, and at page 25, lines 3-11, in Table 1, in the sequence listing, and in the original claims. No new matter enters by these amendments. Upon entry of the foregoing amendments, claims 3, 5-7, 10 and 12-20 are pending in the application.

The specification has been amended to correct typographical errors in the claim for priority to Provisional Application No. 60/130,465. No new matter enters by this amendment.

1. Election/Restriction Requirement

Applicant acknowledges the finality of the restriction requirement but maintains his traversal. To facilitate prosecution, however, Applicant has removed the non-elected claims from the application.

Applicant further acknowledges the finality of the election requirement to a single nucleotide sequence, but maintains his traversal. Applicant submits that election of a single nucleotide sequence is improper and Applicant believes no serious burden would result by the search and examination of at least ten nucleotide sequences. The election of a single nucleic acid sequence contravenes the USPTO policy as set forth in the Manual of Patent Examining Procedure stating that "to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the

Commissioner has decided ... to permit a reasonable number of such nucleotide sequences to be claimed in a single application." (MPEP, 8th ed., August 2001, Section 803.04). The MPEP further provides that "[i]t has been determined that normally ten sequences constitute a reasonable number for examination purposes." (emphasis added) *Id.* While the Examiner requires that a single nucleotide sequence be selected, no reason has been provided for this deviation from articulated Patent Office policy.

Although Applicant disagrees with the election requirement of a single nucleotide sequence, to facilitate prosecution the claims have been amended to reflect the elected SEQ ID NO: 1.

2. Rejection of Claims 3, 5-7 and 9-10 Under 35 U.S.C. § 112, Second Paragraph

Claims 3, 5-7 and 9-10 were rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. Office Action at page 4.

Claims 3, 5 and 6 were rejected for the recitation of "wherein said structural nucleic acid molecule encodes a protein or fragment thereof selected from the group consisting of a *Glycine max* protein or fragment thereof in Table 1" because Table 1 allegedly does not recite a *Glycine max* protein that is related to instant SEQ ID NO: 1. Office Action at page 4.

The Examiner has also rejected all of the claims as being indefinite because "they appear to conflict as to the function of instant SEQ ID NO: 1, and the claimed invention is rendered unclear." Office Action at page 4.

Applicant has amended the claims to clarify the function of a nucleic acid molecule comprising the nucleic acid sequence of SEQ ID NO: 1 with respect to the presently claimed invention. As such, the rejections under 35 U.S.C. § 112, second paragraph, have been rendered moot by these foregoing claim amendments. Reconsideration and withdrawal of this rejection is respectfully requested.

3. Rejection of Claims 3, 5-7 and 9-10 Under 35 U.S.C. § 101

Claims 3, 5-7 and 9-10 have been erroneously rejected under 35 U.S.C. § 101 for allegedly not being supported "by a specific, substantial, and credibly utility or, in the alternative, a well established utility". Office Action at page 5. Applicant respectfully traverses this rejection.

The Examiner acknowledges that Applicant has disclosed several utilities for the nucleic acid molecules of the present invention, including "genetic mapping studies, physical mapping, contig mapping, comparative mapping, the identification of polymorphisms, monitoring expression, locating regions of identity by descent between individuals, isolating clones, microarray based methods, direct site mutagenesis, transformation, in cosuppression, to reduce gene function, and as antibodies." Office Action at page 6 (citations omitted). However, the Examiner contends that none of the utilities disclosed in the present application satisfy 35 U.S.C. § 101 because they are "generally applicable to any nucleic acid". *Id.*

As Applicant has previously stated, the "basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility...where specific benefit exists in currently available form." *Brenner v. Manson*, 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). Applicant has met this part of the bargain – he has disclosed nucleic acid molecules which, in their current form, provide at least one specific benefit to the public, for example use to identify a polymorphism in a population of *Glycine max*. This benefit is specific, not vague or unknown, and it is a "real world" or substantial benefit.

It is well-established law that "when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983). As acknowledged by the Examiner, the specification describes multiple objectives and utilities that are met by the present invention. For example, the claimed nucleic acid molecules are useful in determining the presence of polymorphisms, isolating specific promoter sequences, and

to obtain nucleic acid homologues, *etc.* (*see e.g.,* Specification, beginning at page 35, under heading "Uses of the Agents of the Invention").

Many of these uses are directly analogous to the use of a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell, or organism. Significantly, the utility of a microscope under 35 U.S.C. § 101 is not compromised by its use as a tool in this manner. Many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.,* the claimed nucleic acid molecule may be used to identify and characterize nucleic acid molecules within a sample, cell, or organism. Such utility is indistinguishable from the legally sufficient utility of a microscope. Thus, the presently disclosed sequences possess the requisite utility under 35 U.S.C. § 101.

The Examiner correctly points out that claims in the present application are drawn to constructs, such as transformed plant cells and plants comprising a nucleic acid molecule having a nucleic acid sequence of SEQ ID NO: 1. The Examiner argues, for example, that claims 3, 5 and 6 are drawn to transformed plant cells that have a construct which contains instant SEQ ID NO: 1 as a structural nucleic acid that encodes a *Glycine max* protein, however this is allegedly not a legal utility because "the ability to encode a polypeptide is not specific to SEQ ID NO: 1, but instead is applicable to any polynucleotide." Office Action at page 6.

In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. Claims 3, 5 and 6 have been amended to clarify the role of SEQ ID NO: 1 in a transformed plant cell, however, notwithstanding this the Examiner's position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renshaw PLC,* 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result...").

Moreover, this position offends the sensibilities. For example, such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.,* hitting golf balls. Such a result is not only untenable, but requires

reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty,* 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933). Thus, it must be the case that a utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.

Applicant notes that the claimed nucleic acid molecules encompass many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and isolate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecules will identify a ***unique*** subset of related sequences. This subset of related sequences is specific to the claimed sequence and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit the ball in a manner that is distinct from other clubs.

The Examiner also correctly points out that claims in the present application are drawn to transformed plant cells and plants which contain SEQ ID NO: 1 or its complement as an exogenous promoter region that functions in a plant cell to cause the production of an mRNA molecule. Office Action at page 7. However, the Examiner is not correct in arguing that this is not a substantial utility because "further experimentation would be required to determine which portion of SEQ ID NO: 1, or its complement, or fragments of either would function as a promoter as required by the claims." *Id.*

The specification provides that nucleic acid molecules of the present invention comprise promoter regions or partial promoter regions and associated elements. *See, e.g.,* specification at page 16, line 11 through page 23, line 23. One of ordinary skill in the art would be guided by Applicant's present disclosure to identify regions of SEQ ID NO: 1, its complement, or fragments of either that possess functionality as a promoter.

Furthermore, SEQ ID NO: 1 exhibits significant similarity (e-value 3^{-10}) to GenBank accession number AJ011009. Specifically, the region of similarity between SEQ ID NO: 1 and AJ011009 has been demonstrated to be necessary for promoter activity in *Glycine max* cytosolic glutamate synthetase (Tercé-Laforgue *et al.* (1999), *Plant Molecular Biology 39*:551-564, copy enclosed). Thus, contrary to the Examiner's assertion, one of ordinary skill in the art would recognize the utility of a nucleic acid molecule comprising SEQ ID NO: 1 as a promoter in a transformed plant or plant cell without resort to further experimentation.

Surprisingly, the Examiner states that the credibility of the presently asserted utilities has not been assessed. Office Action at page 9. Credibility is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* The Examiner "must do more than merely question operability – [she] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert,* 524 F.2d 1222, 1224-25, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 2107 ("Office personal are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided...").

Here, the Examiner has not even attempted to meet this burden. Thus, the Examiner's admission that the credibility of the disclosed utilities is not challenged is tantamount to an admission that no proper rejection has been made.

In view of the above, Applicant contends that the claimed nucleic acid molecules are supported by credible, specific, and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. Consequently, the rejection of claims 3, 5-7 and 9-10 under 35 U.S.C. §101 is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

4. Rejection of Claims 1-3, 5-7 and 9-10 Under 35 U.S.C. §112, 1st Paragraph: Enablement

Claims 1-3, 5-7 and 9-10[1] were rejected under 35 U.S.C. § 112, first paragraph, as not being enabled by the specification, because the claimed invention allegedly lacks utility (*i.e.*, an invention with no utility cannot be enabled). Applicant respectfully traverses this rejection, and notes that this rejection has been overcome by the foregoing arguments regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph, is improper. Reconsideration and withdrawal are respectfully requested.

The Examiner further alleges that claims 1-3, 5-7 and 9-10 are not enabled under an analysis of the factors presented in *In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1998). However, the Examiner cites no support for the proposition that the full scope of the claims would require undue experimentation by one of ordinary skill in the art to make or use the claimed invention.

It is well established patent jurisprudence that Applicant needs not teach "conventional and well-known genetic engineering techniques" (*see, for example, Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000)), which would include the use of the claimed sequence with other nucleic acid sequences, Applicant submits the Examiner has not met the required burden. Furthermore, Applicant submits that an analysis of the criteria presented by *In re Wands* supports Applicant's position that no undue experimentation would be required to

[1] Applicant respectfully points out that claims 1 and 2 were cancelled in Applicant's response dated February 19, 2002.

make and use the claimed invention. *See In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1998).

The first *Wands* criterion is the quantity of experimentation necessary. The "make-and-test" quantum of experimentation is reduced by the extensive knowledge, *e.g.*, of conservative nucleotide substitutions, identification of an active site, and radiometric synthase assay conditions, to which a person of ordinary skill in the art has access. Performing routine and well-known steps, such as sequence alignment protocols, molecular weight determination, and antibody hybridization assays, cannot create undue experimentation even if it is laborious. *See In re Angstadt*, 537 F.2d 498, 504, 190 U.S.P.Q. 214, 218-219 (C.C.P.A. 1976).

The second and third *Wands* criteria relate to the amount of direction or guidance given, and the presence or absence of working examples. Again, the specification provides, for example, evidence of sequence identity, discloses start and stop positions within a sequence, promoter or partial promoter regions within a sequence, and discusses the use of the claimed SEQ ID NO to isolate additional sequences within a genome and to create BAC libraries. *See, e.g.,* specification at page 16, line 12 through page 23, line 23, page 89, line 6 through page 100, line 14 (Examples 1-5), Table I and the sequence listing. Based on such disclosure, one of ordinary skill in the art would be enabled to make and use the invention commensurate in scope with the claims.

The fourth, fifth, and sixth *Wands* criteria focuses on the nature of the invention, the state of the art, and the relative skill in the art. The present invention relates to nucleic acid sequences and constructs derived therefrom, and the specification further describes amino acid sequences derived therefrom, antibodies, constructs and methods related thereto. *See, e.g.,* specification at page 24, line 1 through page 29, line 13 (describing polypeptide molecules and homologues), page 62, line 10 through page 80, line 19 (describing use of the claimed nucleic acid molecules in methods of transforming plants), and page 89, line 6 through page 93, line 16 (construction of a BAC library from the nucleic acid molecules of the present invention). Practitioners in this art are guided by considerable knowledge and resources on the conditions and approaches that can be

utilized to identify, confirm, and introduce into other hosts, nucleic acid and amino acid sequences.

The seventh criterion considers the predictability of the art. The Examiner has presented no evidence why one of ordinary skill in the art would not, for example, be able to predict conservative substitutions, identify promoter regions within the claimed nucleic acid molecules, or use the nucleic acid molecules of the present invention in methods of transforming plants. Applicant asserts that the specification discloses sufficient guidance to render these results predictable. *See,* for example, page 24, line 1 through page 29, line 13, page 62, line 10 through page 80, line 19, and page 89, line 6 through page 93, line 16, discussed *supra.*

The eighth criterion focuses on the breadth of the claims. Enablement is satisfied when the disclosure "adequately guide[s] the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility". *See In re Vaeck,* 947 F.2d 488, 496, 20 U.S.P.Q.2d 1438, 1445 (Fed. Cir. 1991). In the present case, one of skill in the art is specifically guided by the disclosure to look to, *e.g.*, sequence identity data in making that determination.

The Examiner has presented no evidence supporting the allegation that one of ordinary skill in the art would not be able to make or use the claimed nucleic acid molecules and constructs in light of Applicant's disclosure. Furthermore, the analysis of the *Wands* factors, discussed *supra*, conclusively establishes that one of ordinary skill in the art would be able to make and use the claimed invention based on the disclosure in the specification. Accordingly, for at least these reasons, the enablement rejection under 35 USC § 112, first paragraph, is improper. Reconsideration and withdrawal are respectfully requested.

5. Rejection of Claims 3, 5, 6, 7, 9 and 10 Under 35 U.S.C. §102

Claims 3, 5, 6, 7, 9 and 10 have been rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Tanksley *et al.* (U.S. Patent No. 5,648,599). Applicant respectfully traverses this rejection.

"It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986). Further, "an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device." *In re Donohue*, 766 F.2d 531, 226 U.S.P.Q 619 (Fed. Cir. 1985). In the present application, pending claims 3, 5, 6, 7, 9 and 10 are directed to constructs comprising a nucleic acid molecule which encodes a *Glycine max* protein or fragment thereof comprising the nucleic acid sequence of SEQ ID NO: 1. The reference cited by the Examiner ("Tanksley") does not disclose SEQ ID NO: 1 in its entirety. The Examiner has applied an untenable interpretation of the claims to cover small fragments of the specifically claimed nucleic acid molecule, *i.e.*, molecules as short as one codon, and peptide sequences as short as one amino acid and thus concludes that the claim is anticipated by the cited reference. Office Action at page 11. A grammatically consistent interpretation of the claim at issue would relate the phrase "or fragment thereof" in the preamble back to the phrase "*Glycine max* protein" directly preceding it. Further, the claims have been amended to eliminate the recitation of a fragment of SEQ ID NO: 1.

As such, the presently amended claims are not anticipated by the Tanksley reference cited by the Examiner. Whatever the Tanksley reference teaches, it does not disclose SEQ ID NO: 1 in its entirety. Absent a teaching of each and every element of the claim, *i.e.*, SEQ ID NO: 1, the reference cited by the Examiner does not anticipate claims 3, 5, 6, 7, 9 and 10 and the rejection should be reversed.

Accordingly, for at least the foregoing reasons, the rejection of claims 3, 5, 6, 7, 9 and 10 under 35 U.S.C. § 102(b) is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

6. Provisional Rejection of Claims 3, 5, 6, 7, 9 and 10 for Double Patenting

Claims 3, 5-7 and 9-10 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-9 and 16 of copending Application No. 09/421,106. Office Action at page 12. As this rejection is provisional, Applicant is under no immediate obligation to respond to the rejection and

respectfully requests that the rejection be held in abeyance until otherwise allowable subject matter is identified in accordance with MPEP § 804. Upon notification of otherwise allowable subject matter, Applicant will traverse or file a terminal disclaimer, as appropriate, if a non-provisional double patenting rejection is applied to the then-pending claims.

7. Rejection of Claims 1-3, 5-7 and 9-10 under 35 U.S.C. § 102(f)

Claims 1-3, 5-7 and 9-10 have been rejected under 35 U.S.C. § 102(f). Office Action at page 14. Applicant respectfully directs the Examiner's attention to the Request for Deletion of Inventor, filed herewith, which amends Inventorship of the present application to reflect the fact that claims directed to subject matter invented by David K. Kovalic have been cancelled in the present Amendment and Response in order to comply with the restriction requirement imposed by the Examiner. Thus, reconsideration and withdrawal of this rejection are respectfully requested.

8. Provisional Rejection of Claims 3, 5-7 and 9-10 Under 35 U.S.C. § 102(e)

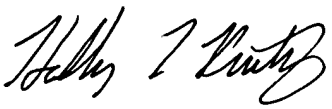
Claims 3, 5-7 and 9-10 have been provisionally rejected under 35 U.S.C. § 102(e) over copending Application Nos. 09/421,106 and 09/521,640. Office Action at pages 12-13. Applicant respectfully directs the Examiner's attention to the amendment to the present specification *supra*, first made in Applicant's Response dated February 19, 2002, which perfects priority under 35 U.S.C. § 120 to Application Nos. 09/421,106 and 09/521,640, and further perfects priority under 35 U.S.C. § 119(e) to Application No. 60/130,465. As such, Applicant has perfected his claim for priority in accordance with MPEP § 706.02(b). In light of this perfected claim, and the deletion of David K. Kovalic as a named inventor in the present application, the provisional rejection under 35 U.S.C. § 102(e) is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

Conclusion

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is now in condition for allowance, and notice of such is respectfully requested. The Examiner is encouraged to contact the undersigned should any additional information be necessary for allowance.

In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Applicants do not believe that any fees in addition to those provided for in the accompanying documents, are due at this time. However, if any fees under 37 C.F.R. §§ 1.16 or 1.17 are required in the present application, including any fees for extensions of time, then the Commissioner is hereby authorized to charge such fees to Deposit Account No. 50-2387, referencing docket number 16517.132.

Respectfully submitted,



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Marked-up Version of Amended Specification

Beginning at page 1, line 3, immediately following the title:

This application is a continuation-in-part of U.S. patent application 09/521,640, filed March 10, 2000, which is a continuation-in-part of U.S. patent application 09/421,106, filed October 15, 1999; this application also claims priority to U.S. patent application 60/130,4**[5]**6<u>5</u>, filed April 22, 1999.

Marked-up Version of Amended Claims

3. (Twice Amended) A transformed plant cell having a nucleic acid molecule which comprises:

(A) an exogenous promoter region which functions in said cell to cause the production of a mRNA molecule**, wherein said promoter nucleic acid molecule comprises SEQ ID NO: 1 or a complement thereof**; which is linked to

(B) a structural nucleic acid molecule**[, wherein said structural nucleic acid molecule]** encod**ing[es]** a protein or **peptide [fragment thereof selected from the group consisting of a *Glycine max* protein or fragment thereof in Table 1]**; which is linked to

(C) a 3' non-translated sequence that functions in said cell to cause termination of transcription and addition of polyadenylated ribonucleotides to a 3' end of said mRNA molecule.

7. (Once amended) A transformed plant having a nucleic acid molecule which comprises:

(A) an exogenous promoter region which functions in a plant cell to cause the production of a mRNA molecule, wherein said promoter nucleic acid molecule **[is selected from the group consisting of]** **comprises** SEQ ID NO: 1, **[through SEQ ID NO: 20082]** or **a** complement**[s]** thereof **[or fragment of either]**; which is linked to

(B) a structural nucleic acid molecule encoding a protein or peptide; which is linked to

(C) a 3' non-translated sequence that functions in a plant cell to cause termination of transcription and addition of polyadenylated ribonucleotides to a 3' end of said mRNA molecule.